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The Explo'Santé mixed methods protocol: an interventional research school health promotion project in France

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Abstract

Background According to WHO, "noncommunicable diseases (NCDs) kill 41 million people" annually, as the primary cause of death globally. WHO's Global Action Plan for the prevention and control of NCDs 2013–2020 (extended) tackles this issue and its implications regarding inequalities between countries and populations. Based on combined behavioural, environmental and policy approaches, health promotion aims to reduce health inequities and address health determinants through 3 strategies: education, prevention and protection. It is a well-known fact that long-term efficiency in health promotion, that is to say the promotion of health and well-being, involves interventions and programmes which target / involve children [1]. As a focal point in communities and a key environment for children, school is an important setting to implement health promotion programmes, especially integrated approaches and interventions targeting Life Skills (LS). Indeed, LS contribute to health and well-being, particularly for pupils. This article presents the research protocol of a French integrated school-based health promotion interventional research programme which intends to support the health promoting schools (HPS) approach in France: Explo'Santé. It results from a partnership between the University of Lyon and the French League against Cancer.

Methods Explo'Santé is an observational study based on a mixed methods research design, which aims to evaluate the effects of a health promotion programme, to elicit its implementation process and identify contextual factors. This 3-year, complex programme targets primary school pupils aged 8 to 10. It incorporates health education sessions, to develop pupils' LS and health literacy (HL), and to promote healthy environments. Teachers and French League prevention officers are trained to support skill development and programme sustainability. Data collection includes quantitative data via questionnaires, to assess programme impact on approximately 700 pupils, as well as 36 teachers, and 6 prevention officers, as well as qualitative data collected via focus groups with pupils, and interviews with teachers, parents, prevention officers, and school heads, to understand the barriers and promoting factors to the

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implementation of the programme, the differences in process and effects in different contexts, and its potential for sustainability.

Discussion Explo'Santé was designed to contribute to school-based health promotion strategies, by including key players, promoting partnerships, targeting multiple levels of impact and effect, and to ensure every step is research-based and informed. Finally, this study aims to identify the elements which would enable Explo'Santé to become a model in France and internationally.

Keywords School health promotion, Interventional research, Protocol, Mixed study design, Evaluation

Text box 1. Contributions to the literature

- Explo'Santé is a French integrated 3-year school-based health promotion intervention research programme that combines health education, LS development, and environmental improvements to address health inequalities in schools.
- Comprehensive evaluation of Explo'Santé's impact and implementation challenges through a mixed methods approach, combining quantitative and qualitative data.
- Identification of critical factors for the programme's sustainability and exploration of its potential for replication across diverse educational contexts.
- Explo'Santé will provide valuable insights into reducing health disparities, presenting a model that can be adapted to different contexts and contributing to the broader goal of equitable health promotion.

Background

According to the World Health Organization, cardiovascular disease, diabetes, chronic respiratory disease and cancer kill 41 million people a year [2]. Noncommunicable diseases (NCDs) have thus been identified as the primary cause of death globally [3–5]. In 2013, to address this issue, the World Health Organization launched its Global Action Plan for the prevention and control of NCDs 2013–2020 (extended to 2030), to reduce "the burden due to noncommunicable diseases" on social and economic development, as well as inequalities between countries and populations [3]. One of the more specific aims of this action plan was "to reduce modifiable risk factors for noncommunicable diseases, and more specifically cancer, as well as underlying social determinants through the creation of health-promoting environments" and the implementation of strategies and policies [6] centred around "health promotion, disease prevention and comprehensive care" [3].

It is globally recognised that programmes rooted in the field of health promotion, *as* "the process of enabling people to increase control over, and improve their health", have the potential to target the systemic, environmental, and individual determinants of health in order to reduce health inequities [7]. Downie, Fyfe and Tannahill propose a threefold model of health promotion interventions, which includes: *Health education* to enable people to make decisions and take action towards their health, notably through the development of their HL and their LS [8]; *Prevention*, which addresses risk factors, protective factors and the consequences of ill-health; and *Protection*, which focuses on public policies and environmental factors [8]. Research has shown that schools are one of the key settings to develop pupils' LS and HL, for prevention strategies as well as interventions on the environment of the children, thus promoting children's present and future health [9]. Indeed, most children attend school from an early age, which enables health promoters to implement programmes targeting children from different backgrounds, cultures and communities, and work on the determinants of health effectively [10, 11].

Against this backdrop, researchers have strived to understand how programmes and interventions can best be implemented efficiently in schools, as schools' primary focus is not set on health. The main activity of schools is focused on disciplinary learning and school activities rather than health issues. In terms of the efficiency of school-based health promotion, integrated approaches such as the whole school Health Promotion Schools framework are now widely recognised as particularly relevant. As adaptations of this framework and various forms of its translation may be found in worldwide practice, Langford et al. identified the following 3 main components of this framework [12]: a curriculum which formally integrates health, a school ethos and environment conducive to health and well-being, and strong relations with families and the wider community [12]. The curriculum of a health promoting school should include the development of heath literacy as well as LS, which are defined as "the abilities for adaptive and positive behaviours that enable individuals to effectively deal with the demands and challenges of everyday life" [13]. Pupils are encouraged to improve their decision-making and problem-solving skills, develop creative and critical thinking, self-awareness and empathy, communication skills and interpersonal skills, and coping with emotions and managing stress: indeed, research has shown the benefits of LS development and education in protecting health [14], in reducing health-compromising behaviour [15–17], and in fostering well-being, mental health, cognitive development and academic achievement [18–20]. However, it is important to note that efficient LS interventions rely on regular pupil exposure (vs. one-shot interventions), through sessions of 1 to 2 h, organised in

modules of 20 h minimum, over several years and must be evidence-based [20, 21].

Another challenge lies in the fact that the evaluation of LS development remains difficult for researchers, both quantitatively and qualitatively, as no consensual evaluation framework nor scale exists [22]. Nonetheless, one of the evidence-based strategies to measure the impact of LS programmes in the literature is to use associated concepts such as health literacy (HL), self-efficacy (SE) and life satisfaction (LSa) [20, 23, 24]. In order to ensure clarity, let us define here LS and the concepts in question: (i) LS "are the abilities for adaptative and positive behaviour that enable individuals to deal effectively with the demands and challenges of everyday life" [25]; (ii) HL is "The ability to make sound health decision(s) in the context of everyday life - at home, in the community, at the workplace, the healthcare system, the marketplace and the political arena. It is a critical empowerment strategy to increase people's control over their health, their ability to seek out information and their ability to take responsibility" [26]; (iii) according to Bandura, SE is the belief in one's capacity to achieve one's goals or complete a task successfully [27]; finally, (iv) LSa is a cognitive appreciation of the positive aspects of life, both from a broad perspective and within specific life domains, such as the self, family, school, friends and living environment [28].

Furthermore, another point of tension documented in the international literature concerns the implementation of complex health promotion programmes. The implementation of particularly complex programmes cannot be limited to a "plug and play" process. What actually happens often differs from what had been previously anticipated and planned [29]. The differences observed between what had been planned or anticipated when designing the intervention and what occurs in the field are due to multiple and interdependent contextual factors [30, 31]. These contextual factors influence the way in which the programme is accepted and determine whether the programme is implemented and sustained as intended. One could bring forward the understanding and vision of the role of the school in promoting health [32, 33], the availability of staff [33], or the inclusion of support and training in the programme [34] as some of the contextual factors which will influence the implementation process. Furthermore, interventions in schools are numerous, and requests to National Education staff are constant. An additional difficulty is to install programmes sustainably in establishments even when the partner in charge is no longer present.

Also, the impact and effect of health promotion programmes are created over time from complex interactions [35–38]. This point is extremely important because it influences greatly the choice of the evaluation framework. Programme evaluation, especially in public health and health promotion, often consists in determining whether the impact was achieved as expected by the project leaders [39]. However, in the case of complex programmes, mobilising relevant evaluation frameworks is no easy task, however critical [36], as they require to be consistent with the ecological perspective, which underlies the design of health promotion programmes, taking into account the determinants of health and the reduction of health inequalities. Timmins and Miller emphasise that ecological evaluation frameworks based on programme theory (for example, realist evaluation [40]) are consistent with this perspective [41], as both effectiveness and implementation process are in focus, including the way in which contextual factors influence the implementation process.

The aim of this article is to present the research protocol designed to address the points of tension presented above, using the example of a French complex school-based health promotion programme named Explo'Santé. It was submitted for funding as a 3-year interventional research project resulting from the partnership between the Health Systemic Process research unit UR 4129 at Claude Bernard Lyon 1 University (research lead) and the French League against Cancer (intervention lead). It is also a permanent concern of the League against Cancer to better understand the reasons why the dynamics initiated by their interventions do or do not continue, beyond their departure. The research design aims to understand the implementation process, from adhesion and implementation of the programme to its sustainability and potential for replication or transferability [42].

Description of the programme

This programme was designed over the course of a ten-year collaboration with the French League against Cancer as a school-based health promotion intervention. The programme was also intended to piggy-back onto the current focus on HPS in France. The General Directorate for School Education and the French Public Health Agency have indeed highlighted the relevance of the intervention strategies for developing whole-school HPS in France, especially those that also intervene on the environment, whether social (social cohesion, communication rules, shared values, relational climate, etc.) or physical (built environments and spatial planning). The Explo'Santé programme was precisely designed with this in mind, thanks to the knowledge and feedback from previous experiments by the two partner teams involved. It also draws on the French political agenda, particularly the 2021 National Institute against Cancer strategy to support intervention research. However, from a conceptual point of view, one may be confused as to whether this project relates to school-based health promotion (out-of-school providers introducing a project often

designed without the school involved) or the HPS framework. Nevertheless, from our experience with our European partners, we have found that, in fact, ours is not an unusual situation, as each country, each provider, each project leader translates the framework into what they understand of it, make sense of, and more importantly can do. In order to make this clearer for the reader, it is not a matter of choosing either / or, but rather to articulate the two frameworks. The programme is a school-based intervention which aims to support the schools into becoming or strengthening the HPS framework, as it includes staff training, health education, interventions on environments and the development of collaborations with the school community [43, 44].

Methods

Study design and research questions

The design of this intervention research takes its root in implementation science [45], theory-based evaluation models [46] and realistic evaluation [47] to understand what components of the programme work, in what context, how, and for whom. The design for this programme evaluation was chosen to be consistent with complex programmes evaluation frameworks [36]. Timmins and Miller emphasise that theory-based evaluation [40] enables the evaluator to explore multiple levels of changes introduced by the programme, but also the way in which contextual factors influence the implementation process [41] and the immediate health promotion outcomes (programme impact measures) [48, 49].

3 aspects of implementation science [50] were chosen as leads for this research: (i) evaluation of the *implementation process*, (ii) the implementation of the programme in terms of its *trajectory* (initiation, adherence, adaptation, and sustainability), (iii) evaluation of the *effects*, *impact*, and understanding the *determining factors*. This will therefore involve:

- understanding how the programme was implemented in the different school contexts [51]; which components of the programme did or did not work and why [41, 42]; identifying contextual factors which had a positive or negative influence on the impact and effect of the programme as well as its implementation [29]; understanding how these contextual factors act both on the impact but also on the process of its implementation [40, 52, 53].
- understanding the adhesion mechanisms, the necessary adaptations, and the potential for sustainability of the Explo'Santé programme in the different contexts;
- assessing the impact of each component of the programme (impact is referred to as the immediate results of the project on the target population, consistent with the underlying explicit theory of change [38].)
- assessing the effects of the programme. Effects are referred to as other outcomes resulting from the implementation of the programme, whether expected or not [40], (e.g. health capacity building [54], organisational changes, changes in leadership or partnership, institutional changes [55], pedagogical and curriculum innovation, evolution in programme content), or negative outcomes (e.g. stress, work overload, tensions the project being dropped, dissolution of the partnership) [29, 30, 42].

Note This research project was designed by the principal investigator to fuel multiple PhDs.

The choice of mixed methods

Creswell and Plano Clark's explanatory mixed method framework provided the background for the choice of mixed methods for this project. It entails collecting quantitative data first. Then the qualitative data serves to explain any findings from the first round of collection. Explanatory mixed methods require two phases of data collection. The qualitative data set will serve to shed light on quantitative results, but also enable the research team to identify gaps. Creswell and Plano Clark also point out that triangulation is relevant when striving to understand a complex phenomenon and explore multiple levels within a system (the system in focus in the present research being schools) [56–58]. This is consistent with Guevel et al.'s argument for the relevance of an embedded QUAN(Qual) mixed method research design for health promotion [59]. The quantitative data intend to measure putative changes introduced by the programme, while the qualitative data shed light on the quantitative data, explore the effects of the programme (as defined above), and the contextual factors at play, which require the perspective of stakeholders in order to be understood fully. Let us recall that Guével et al.'s suggestion to use mixed methods as an added value to the evaluation of school health promotion complex interventions was justified by the possibility of encompassing interdisciplinarity, and the uncertainty of outcomes (short- or long-term) in a case where causality between a programme and its outcomes is non-linear (which is the case with Explo'Santé as a multi-layered complex health promotion programme). Finally, the choice for this design was also rooted in previous realist evaluation work from the project's principal investigator [29, 60], where methods and data triangulation [61] were ensured so that more in-depth knowledge was acquired.

Outcomes of the intervention research programme

In accordance with health promotion interventional research approaches [62], this intervention research programme aims:

(i) to produce favourable impact on pupils and adult stakeholders, and effects on the setting, the stakeholders or the programme itself; and explore the process of implementation but also.
(ii) to document and produce knowledge on how the programme worked, why and under what circumstances, using an evidence-based and evidence-informed research approach [63]. This will be the basis for recommendations regarding the further development (sustainability, replication, transferability etc…) of such programmes as well as their evaluation.

Impact of the programme

The implementation of this programme should contribute to the development of pupils' HL, LS, SE and LSa. Additional impact is expected in the form of the development of the skills, knowledge and know-how of the trained stakeholders, especially in terms of skills to design and implement health promoting actions/interventions, as well as stakeholders' satisfaction with the training programme, which is a known factor to programme sustainability [60].

Effects of the programme

It is also anticipated that the programme will trigger a change in teachers' attitudes following the training, especially those in favour of pupil wellbeing. It could also improve networking and collaboration between school and out-of-school partners such as, but not limited to, the League against Cancer. Indeed, it should strengthen the coherence of the actions carried out. It should also ensure continuity between school years, which, in turn, should improve sustainability, which would be in favour of the HPS framework. Consistently with the framework of Pawson and Tilley, the design of this protocol will also take into account unexpected outcomes (possibly negative or unanticipated) [40].

Purpose of data collection

Quantitative data

The collection of quantitative data will enable the research team (i) to evaluate the impact of programme on pupils using the following validated scales and questionnaires: (i) an SE questionnaire (17 questions, 6-item Likert scale) [64], an LSa questionnaire (30 questions, 4-item Likert scale) [28], an LS questionnaire (30 questions, 5-item Likert scale) [14, 23], and an HL questionnaire (10 questions, 4-item Likert scale) [65]; (ii) to assess teachers' satisfaction in terms of expectations, teaching material, activities, relevance and duration, after the training course; (iii) to evaluate the skills developed by the teachers after the training course; (iv) to appraise the practical application of the knowledge and the skills acquired by the teachers and the League prevention officers. The HL, SE and LSa scales used in this research protocol were aimed at French pupils aged respectively 13–16, 10–12 and 15–17. A pre-test was carried out with a sample of 10 pupils aged 8 to 10 to ensure the questionnaires were suitable for the age range of our sample population. The research ethics committee "Comité d'Éthique pour les Recherches Université de Lyon" cleared the quantitative protocol under the reference 2023-01-12-004. The protocol was established in compliance with the methodology of reference MR004 by the National Commission for Informatics and Liberty (Conseil National Informatique et des Libertés), under the reference 2,226,244 v0.

Qualitative data

The qualitative data will enable the team to further understand the results of the quantitative data, more specifically (i) to identify the barriers and the promoting factors to the implementation of the programme, (ii) to understand potential differences between the different contexts in terms of process and effects, and (iii) to understand whether and how Explo'Santé can be sustainable and could be replicated in other French regions. The data collected will elicit which components work and why; how the programme was adopted, the adaptations made and why, as well as the unanticipated effects of the programme.

Anonymity is ensured by coding the names of the school and participants. The data is stored and transmitted securely, guaranteeing anonymity. Feedback on the research results is provided by local teams at the request of participants. The ethics committee "Terre d'Éthique", University Hospital Centre of Saint-Etienne, France, cleared the qualitative protocol under the reference IRBN962023/CHUSTE. The protocol was established in compliance with the methodology of reference MR004 by the National Commission for Informatics and Liberty (Conseil National Informatique et des Libertés), under the reference 2,226,244 v0.

Study setting

The study takes place in France. It involves 43 primary schools distributed in 34 towns, spread over 6 *départements* (French national administrative divisions, henceforth referred to as *districts*). 4 towns are involved in the Ardèche district, 11 in the Corrèze district, 6 in the Hérault district, 11 in the Ille-et-Vilaine district, 1 in the Loire and 1 in the Loire-Atlantique. The 61, 4th grade classes from the 43 primary schools involved,

participated in the programme during the first year of the study.

Each school district volunteered to take part in the project after it was presented by the local committees of the French League against Cancer. This approach was favoured to ensure engagement, motivation and participation over the 3 years of the study [29].

Description of the programme

Explo'Santé consists of a school-based health promotion programme which includes approximately 630 pupils from the 4th grade to the 6th grade (aged 8 to 12) in France over three years. The French League against Cancer prevention officers oversee the implementation of the programme in schools. Drawing from a multi-level [66] and complex [67] perspective, the programme focuses on all the determinants of health. It includes:

- (i) A training course aimed at the teachers whose classes are taking part in the programme.
- (ii) The development of healthy social and physical environments for pupils, based on a state of play carried out by the whole school community.
- (iii) The implementation of 10 health education sessions each year.

The training course aimed at the prevention officers was co-constructed by the French League against Cancer and the French ministry of National Education. It was notably based on LS programmes, such as the French adaptation of Unplugged, a prevention programme for secondary school pupils developed by public health professionals and researchers in Europe.

In the initial phase, the programme was introduced by the League prevention officers to the schools and the local administrations involved. The implementation of the programme started in November 2022 and will finish at the end of 2025. The inclusion of study participants started in February 2023 and will continue until the end of 2025.

Teacher training sessions

The teacher training sessions are carried out by the prevention officers. The course aims to develop the skills required for the implementation of the programme, and to promote interaction between the teachers and the other stakeholders. This phase also serves to collect elements towards the state of play. This 2-day course is set to take place every year before the beginning of the 10 health education sessions. It covers the following topics:

- the concepts of health, health promotion and health education, LS, the HPS approach, the presentation of the objectives, the content and the planning of the 10 health education sessions, as well as the platform to access the learning material.

In addition, 2 half-day meetings halfway and at the end of the school year are dedicated to analysing, sharing and assessing practices. During the first school year, the 2-day teacher training took place between November 2022 and January 2023 (See Supplementary file Details about the training sessions from the Explo'Santé project submission).

The promotion of healthy social and physical environments

The second component of the programme, which started in November 2022, includes two stages:

- In the first stage, is a state of play to assess the needs in each school. This is carried out by the prevention officers, in collaboration with the HPS referral team from the Directorate General for School Education, through interviews with local education representatives and local institutional stakeholders.
- The second phase involves the planning, implementation, and evaluation of priority actions.

Health education sessions

The sessions are co-animated by the League prevention officers and the teachers using interactive methods which draw on practical activities, like role-play or the sharing of experiences and knowledge building. The following topics are grouped in 3 modules:

- "Knowing myself better to take care of my health" (4th grade). Pupils aged 8 to 10–75-minute sessions.
- "My day-to-day health in my environment" (5th grade). Pupils aged 9 to 11– 75-minute sessions.
- "Health, the others and I" (6th grade). Pupils aged 10- to 12-year-olds – 60-minute sessions to adapt to middle school schedules.

The first 10-session module began in April 2023.

Study population

The quantitative part of the study involves the cohort of pupils, their teachers, and the League prevention officers. The qualitative part of the study involves some of the pupils who take part in the quantitative part of the study, some of their parents, some of their teachers, some of their school head teachers and principals, and the League prevention officers. Participation was voluntary. The 6 prevention officers, who were involved in the day-to-day field work, made an open call for voluntary participation. The first 2 parents / 2 teachers / 2 school heads / 2 groups of pupils (5 to 8 participants) per district to come forward were included. This selection process was rooted

in a practical and opportunistic approach, considering that in the face of a pluriannual project, which involved multiple rounds of data collection, the risk of participants dropping out or a lower motivation to contribute was non-negligible. The number of participants was limited on purpose, based on the research team's manpower and resources for this project (See Supplementary file Details about the training sessions from the Explo'Santé project submission for mitigation measures to keep participants involved in both the project and the research).

Pupils

Parental consent to participate in quantitative data collection is collected via a letter and a consent form addressed to the pupils' parents, handed out by the teachers. The pupils are also asked for their oral consent at the beginning of each quantitative data collection session.

The inclusion criteria to take part in the quantitative study are: (i) Pupils in the 4th grade (during the 2022/2023 school year), 5th grade (during the 2023/2024 school year) and 6th grade (during the 2024/2025 school year), (ii) who are enrolled in one of the schools taking part in the programme, (iii) who agree to participate in the study by giving their informed oral consent, and (iv) whose parents have provided their informed consent. The exclusion criteria are: (i) pupils who do not read and understand French fluently because the scales were not validated for them, (ii) pupils who have not given their informed oral consent to participate in the study, (iii) or whose parents have not given their informed consent to participate in the study.

To ensure statistical robustness, the pupil sample size was estimated at 385 using the Cochran Formula, with $\alpha = 0.05$, $p = 0.5$ and $Z = 1{,}96$. Our estimated sample population is 700, which exceeds the calculated minimal sample.

The inclusion criteria to take part in the qualitative study are: (i) pupils involved in the quantitative part of the study, (ii) who have given their informed oral consent to participate in group interviews, (iii) whose parents have not opposed their involvement in the qualitative part of the study.

The exclusion criteria are: (i) pupils who are not involved in the quantitative part of the study, (ii) who have not given their informed oral consent to take part in group interviews, (iii) whose parents have disagreed with their involvement in the qualitative part of the study.

Teachers and the league prevention officers

The teachers are recruited through an e-mail or a letter.

The inclusion criteria to take part in the quantitative study are: (i) teachers or League prevention officers, (ii) who take part in the implementation of the programme, (iii) who have given their informed consent to take part in the study. The exclusion criteria are: (i) non-participants in the programme, (ii) participants who do not agree to take part in the study.

The teachers who participate in the qualitative part of the study are contacted by the League prevention officers via an e-mail or a letter, and an information sheet. Upon reception of these documents, they voluntarily join the study. The inclusion criteria are: (i) Teachers in 4th grade (during the 2022/2023 school year), 5th grade (during the 2023/2024 school year) and 6th grade (during the 2024/2025 school year), or League prevention officers, (ii) who are involved in the implementation of the programme, (iii) and who have given their informed consent to participate in interviews. The exclusion criteria are: (i) teachers who are not participating in the implementation of the programme, (ii) teachers who have not agreed to take part in interviews.

Parents

The parents involved in the qualitative part of the study are contacted by the League prevention officers via an e-mail or a letter containing the information sheet.

The inclusion criteria are: (i) parents of a pupil involved in the programme, (ii) who volunteer to participate in an interview by informed consent.

The exclusion criteria are: (i) not being the parent of a pupil involved in the programme, (ii) a parent who has disagreed to participate in an interview.

School head teachers and principals

The school head teachers and the principals who participate in the qualitative study are contacted by the League prevention officers via an e-mail or a letter containing the information notice. Upon reception of these documents, they voluntarily join the study.

The inclusion criteria are: (i) head teachers or principals from one of the schools involved in the implementation of the programme, (ii) who have given their informed consent to participate in an interview.

The exclusion criteria are: (i) head teachers or principals from schools which are not involved in the programme, (ii) head teachers or principals who have disagreed to take part in an interview.

Data collection

The data collection for the Explo'Santé project is described in Fig. 1.

Quantitative study

Pupils' levels of self-efficacy, life satisfaction, life skills and health literacy Each pupil answers 4 questionnaires, either online via tablets, or in paper format in the event of a technical problem, at T0 (baseline, before the initiation of the programme), T1 (at the end of the 4th grade

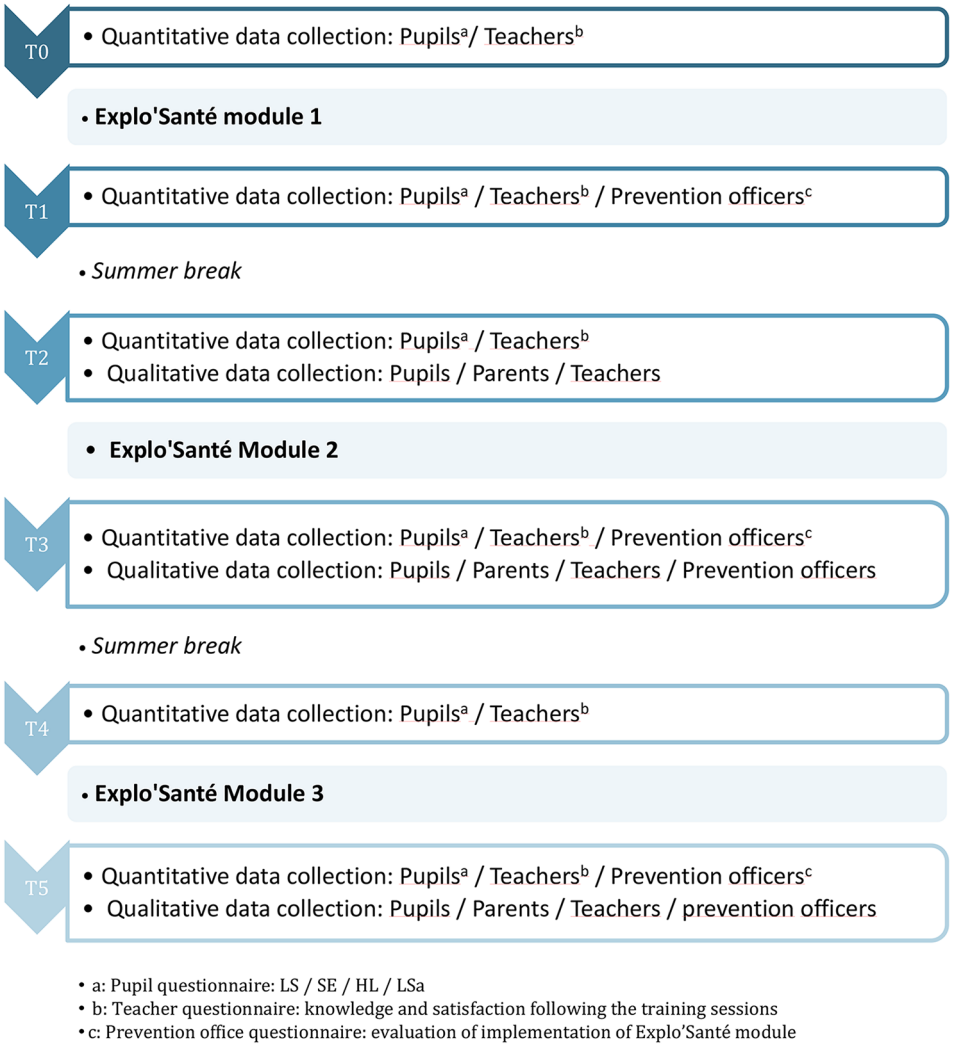

Fig. 1 Sequencing of the Explo'Santé research from T0 to T5

school year), T2 (before the beginning of the programme of the 5th grade school year), T3 (at the end of the 5th grade school year), T4 (before the beginning of the programme of the 5th grade school year) and T5 (at the end of the 5th grade school year) (Fig. 2). The pupils can take a break when they feel like it to counteract the bias of fatigue. The questionnaire sessions are supervised only by the researchers, who ensure the pupils answer the questionnaires autonomously without adult intervention. Any questions asked by the pupils are to be answered solely by the researchers.

The 4 questionnaires are: (i) a SE questionnaire (17 questions, 6-item Likert scale) [68], (ii) a LSa questionnaire (30 questions, 4-item Likert scale) [69], (iii) a LS questionnaire (30 questions, 5-item Likert scale) [23, 70] and, (iv) a HL questionnaire (10 questions, 4-item Likert scale) [65].

Evaluation of the knowledge and the satisfaction of teachers following the 2-day training course The teachers answer 2 online questionnaires at T1 (4th grade teachers), T3 (5th grade teachers) and T5 (6th grade teachers).

The first, composed of 10 multi-choice questions developed by our team, evaluates the knowledge acquired (Supplementary file Questionnaire 1). The second one, composed of 7 questions (5-item Likert scale), determines the level of satisfaction for the training they received (Supplementary file Questionnaire 2).

Firstly, a literature review was carried out to identify relevant questions, as no validated questionnaire was available. Then, when constructing the questions, we ensured that they were clearly formulated, taking care to avoid bias. A pre-test was then carried out on a small sample of teachers to check understanding of the questions and gather feedback. Following this pilot phase,

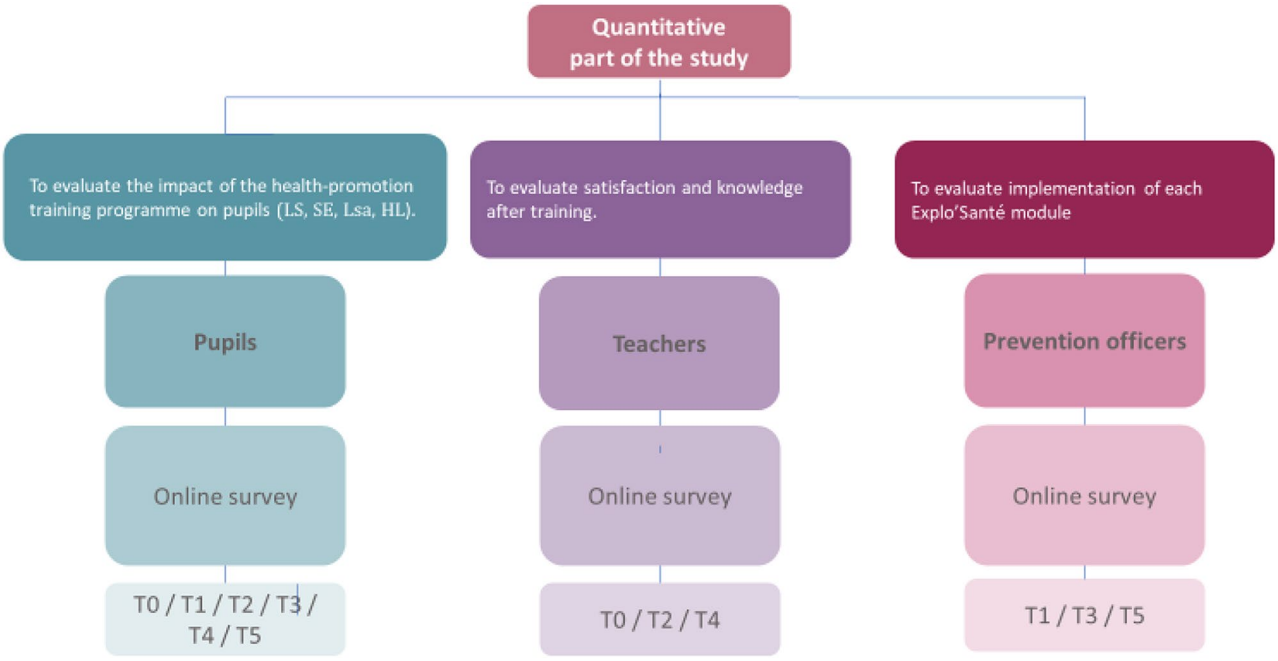

Fig. 2 Presentation of the quantitative part of the Explo'Santé research

revisions were made to improve the clarity and relevance of the questions.

Evaluation of the implementation of each Explo'Santé module by the teachers and the League prevention officers in terms of partnership, pupil engagement, training, objectives and competence development and appropriation: The teachers and the League prevention officers answer an online questionnaire at T1 (teachers of the 4th grade and the League prevention officers), T3 (5th grade teachers and the League prevention officers) and T5 (6th grade teachers and the League prevention officers).

The questionnaire, composed of 10 items (9 Yes/No questions and 1 open-ended question), assesses the implementation of each module of the programme (supplementary file Questionnaire 3) in terms of partnership, pupil engagement, training, objectives and competence development and appropriation.

Qualitative study

Individual interviews with parents, League stakeholders and school leaders (primary and secondary school heads) will allow participants to express the meaning of the surrounding conditions and context [23] in their own words [71], to explore the impacts of the programme that were not apparent in the documents, as well as the specific circumstances, conditions and factors that influenced the implementation process and the impact of the programme. This will also enable the exploration of the necessary adaptations, the mechanisms and factors impacting adhesion to the programme, as well as the potential for sustainability.

Focus groups with pupils will allow participants to understand how the program was implemented in different contexts; which components of the program worked on the pupils who followed the health education sessions the previous year, and why; to understand the adoption mechanisms, the adaptations required and the potential for sustainability of the Explo'Santé programme in the areas concerned; and to evaluate the impact and the effect of the programme on the pupils in terms of life skills development. The interviews and focus groups are audio-recorded, transcribed, and anonymised (Fig. 3).

A reflection logbook was also co-developed with the teachers and stakeholders involved in the training and interventions. They will thus be able to record any other relevant information throughout the project, regarding the results, and how they explain them, the processes at play as well as unexpected items.

Analysis of the Explo'Santé programme through the pupils' perspective Three focus groups of 5 to 8 children per district are conducted (T2, T3 and T5). The pupils are different at each time.

The T2 focus group is organised in 3 parts (Supplementary file Table 1). First, a drawing activity [72] determines the children's representations of the programme. Secondly, a word cloud activity [73] identifies the feelings and emotions associated with the programme. Thirdly, an open discussion about the programme allows for the collection of additional comments and perspectives.

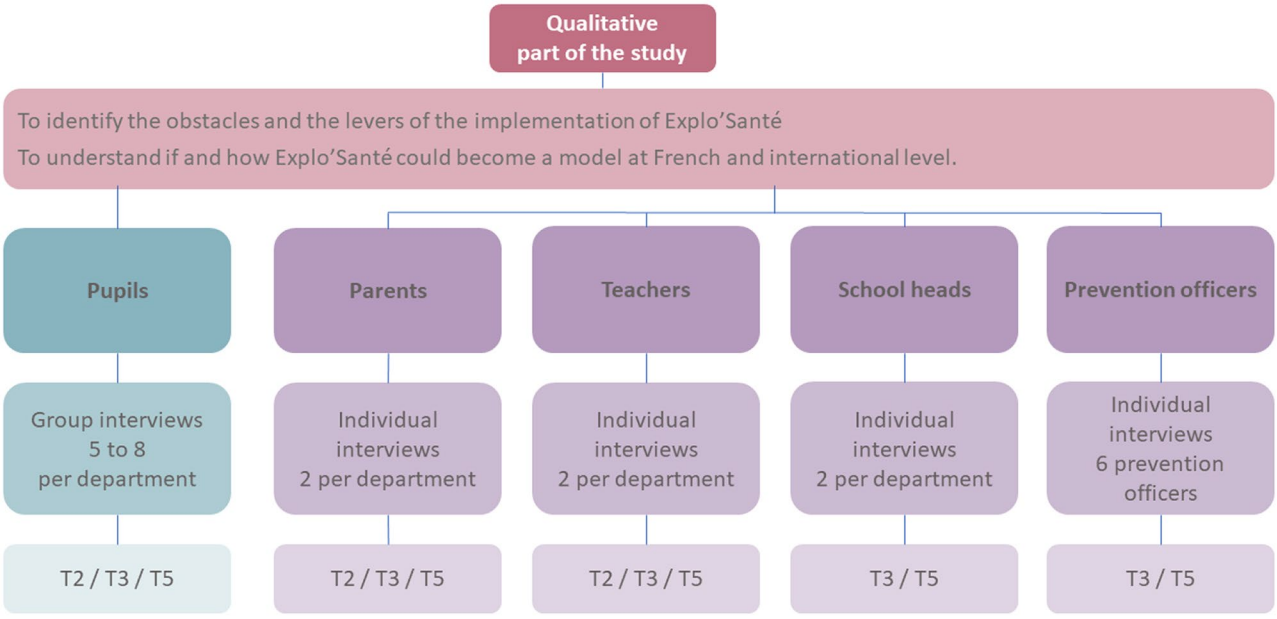

Fig. 3 Presentation of the qualitative part of the Explo'Santé research

The T3 focus group is organised as a group discussion to explore 4 topics: programme expectations, the potential for programme sustainability, implementation and any additional comments and perspectives (Supplementary file Table 2).

The T5 focus group is organised as a group discussion facilitated with the Cube [74] to explore 6 topics: programme expectations, perceived and unexpected effects of the programme, satisfaction, potential for sustainability, implementation and suggestions for improvement (Supplementary file Table 3).

Analysis of the Explo'Santé programme through the League prevention officers' perspective Two semi-structured interviews are conducted (T3 and T5) with each League prevention officer (Supplementary file Tables 4 and 5).

The T3 semi-structured interviews explore 7 topics: adhesion factors, task redefinition, contextual factors, and adaptations, promoting factors, the people involved, project expectations and perceived added value.

The T5 semi-structured interviews explore 6 topics: implementation, setting, collaboration with the school, impact and effects on children and teachers, promoting factors and potential for sustainability.

Analysis of the Explo'Santé programme through the teachers' perspective Semi-structured interviews are conducted at T2 (4th grade teachers), T3 (5th grade teachers) and T5 (6th grade teachers). These interviews explore 14 topics (Supplementary file Table 6).

Analysis of the Explo'Santé programme through parents' experiences Semi-structured interviews are conducted at T2, T3 and T5. These interviews explore 11 topics (Supplementary file Table 7). The parents are different each time.

Analysis of the Explo'Santé programme through school head teachers' and principals' experiences Semi-structured interviews are conducted at T3 (school head teachers) and T5 (school principals). These interviews explore 12 topics (Supplementary file Table 8).

Data analysis

Two levels will be considered for the analysis

- - a meta level: which will provide an overview of the 6 districts concerned, to evaluate the implementation process of Explo'Santé as a meta-intervention; to evaluate the effects and impact of its implementation in schools, to identify common points and essential operational components, necessary adaptations and the potential for sustainability, as well as common contextual factors.
- - a local level: which will consist of Case Studies [75] focused on the local intervention to acquire a more detailed understanding of the implementation dynamics, to evaluate the implementation process in each district and in each school; to identify contextual factors and their mechanisms of action, identify factors of adhesion, and sustainability.

As stated above, the quantitative data will produce scores to evaluate the impact of the programme, in terms of the level of satisfaction and the knowledge learnt by teachers through the training programme, implementation according to teachers and prevention officers, as well as the impact of the Explo'Santé modules on pupils.

The qualitative data will enable the research team to make sense of the quantitative results and identify the mechanisms and contextual factors at play in such results (See realist evaluation framework).

Quantitative content analysis

Pupils' answers to the questionnaires are to be coded with RStudio on a scale from zero to the number of possible answers minus one. Scores will be calculated based on the sum of each answer, both general for each scale, and by category. Pupil population scores will be described both on a global scale and according to district and gender, and Paired Sample T-Test will be used to determine significant statistical differences between the scores obtained before and after the programme.

To provide insight and enrich the qualitative part of the study in terms of context, the data collected with stakeholders will be analysed through frequency. Teachers' answers to the post-training knowledge and satisfaction questionnaires will be compared by district, through Chi-squared tests. For League prevention officers' answers, no statistical test will be performed, due to the limited sample size.

Qualitative content analysis

Qualitative content analysis method will be undertaken [76]. Transcriptions will be read several times to acquire the global sense of each verbatim and coded using the NVIVO qualitative data analysis software (QSR International Pty Ltd. Version 12, 2018). Then codes will be sorted into categories and themes. Concerning the focus groups, the drawings made by pupils and the sticky notes written during the word cloud activity will be analysed and matched to the verbatim.

Discussion

The Explo'Santé programme was designed to contribute towards improving school-based health promotion strategies, by including key players and promoting partnerships. For a pupil, being healthy will improve school achievement [12, 18, 77]. In addition, Explo'Santé was designed to address health inequities as they develop from an early age [78]. Furthermore, school being a place where different players can meet and work together on collaborative and intersectional health promotion strategies [79, 80], providing support and training seems particularly relevant. The multi-layered evaluation design proposed in this research project aims to explore the impact of Explo'Santé on pupils and adult stakeholders, i.e. the change generated [81], as well as its effects on other players in the implementation process, whether anticipated or unexpected, positive or negative [40], while ensuring that every step is research-based and informed. The research design for Explo'Santé stems from a complex perspective of programme evaluation. As the implementation process cannot be limited to a "one size fits all" "plug and play" process, evaluation requires encompassing the differences with what was previously anticipated and planned [82], that is to say to identify and to understand the influence of interdependent contextual factors [31, 83]. The research design is an attempt to propose a complex comprehensive multi-level evaluation framework. The considerable dataset which will be collected will support more research on programme implementation and evaluation in the field of health promotion. It will hopefully contribute to advancing the field of complex theory-based evaluation, at least by pointing out gaps and adding knowledge to existing research. It was also intended as the real-life testing of such complex evaluation frameworks, which will most probably be improved after completion.

As indicated by the state of the art, health promotion from an early age requires a multi-actor, interdisciplinary and integrated approach, particularly in schools. The Explo'Santé project was designed with this in mind, and will provide a better understanding of how to develop the framework of HPS in France, taking into account the variability of school contexts and partners; to propose strategies on how to implement interventions to develop pupils' social skills, as well as to assess their potential impact; and to strengthen the links between research and interdisciplinary practices. With a view to promoting the results of this project, a dissemination and communication plan will be developed so that the deliverables, recommendations and results are easily accessible to all stakeholders concerned in France and beyond.

Explo'Santé is also a significant opportunity to implement a LS development programme in primary schools in France, based on an integrated health promoting framework inspired by the HPS framework [12], and to evaluate its impact. It will gather elements on the relevant strategies to consider when introducing and implementing a complex intervention. It will also explore how the HPS framework may be implemented in France, in terms of context and partnership variability, and sustainability.

Regarding expected outcomes for pupils, levels in HL, SE and motivation, LSa and LS development are anticipated to increase year by year and overall. Indeed, this is the main prospective outcome for the quantitative part of the study protocol. Finally, results regarding the development of competences and knowledge by the teachers and prevention officers are also expected.

Finally, this research intends to contribute to the existing body of knowledge relating to the implementation of successful health promoting interventions. The data collected will enable the team to better understand the implementation dynamics of a programme such as Explo'Santé and, more broadly, complex health promotion programmes in schools. The research team aims to make recommendations as to the relevant strategies for introducing/initiating, implementing and sustaining such programmes in schools. The team also intends to discuss whether the strategy of combining a "starter" intervention carried out by a partner external to the school, with an organisational approach, is relevant or not; and whether some elements are transferable/reliable in other contexts [42], and potential elements for improving the Explo'Santé programme with a view to its transferability/replication and sustainability.

Strengths and limitations

Firstly, to our knowledge, it is the first complex interventional research project to be carried out and evaluated in France, over the course of three years, on the development of HL, LS and healthy environments in a school setting. Secondly, the methodology and analysis of the data collected within the scope of the study relies on a complex evaluation design rooted in recognised evaluation models. Health promotion programme outcomes are not the result of a linear causal relationship and are created over time from complex interactions [35–38]. However, programme evaluation often seeks to understand whether the programme was implemented as planned. This is not the case in this project, which proposes to evaluate impact but also effects on different levels, and most importantly, to understand how such effects were generated. The same perspective is applied to process evaluation, which will enable the research team to collect valuable knowledge for future project leaders and researchers who wish to design complex school-based evaluation programmes. Thirdly, it proposes an interdisciplinary, intersectional and integrated approach with a research design based on data and methods triangulation [84, 85], which combines interventional research, process evaluation and qualitative and quantitative data collection with a variety of players (pupils, teachers, prevention officers, school heads, parents), and a multiplicity of sources (surveys, interviews, meeting minutes) to ensure the widest scope may be reached in terms of results.

It could be argued that a limitation lies in the fact that Explo'Santé does not include a control group. Instead, the progression of each pupil in terms of LS, HL, LSa and SE is monitored to be consistent with the evaluation model chosen for this research.

In terms of other potential limitations, this study is conducted in small-town schools and rural areas in France. It is thus representative of a particular type of setting, which has seldom been explored. Perhaps it would have been interesting to include more urban areas in the study for a more comprehensive perspective on the situation. Indeed, to our knowledge, no data is available on pupils' levels of HL, LS, LSa and SE in France.

Finally, since French is required to take part in the study, non-French-speaking pupils who do not have sufficient command of French have to be excluded. Addressing this issue with the assistance of translators was discussed. However, it was rejected, as this may induce miscomprehension and influence answers. The pupils concerned may be included in the future, if their command of French allows them to do so.

Abbreviations

NCD	Noncommunicable disease
LS	Life Skills
NCDs	Noncommunicable Disease
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1

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Author contributions

Conception: E.D.; L.F.; Drafting of the article: E.D.; A.D.B. M.O.; C.S.; F.C.; Revision of the article: E.D.; A.D.B.; C.S.; F.C.; Obtaining of funding: E.D.; E.R.; Final approval of the article: E.D.; F.C.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical approval

The quantitative study protocol was approved by the ethics committee "Comité d'Éthique pour les Recherches Université de Lyon", Lyon, France (ref 2023-01-12-004) on 1st March 2023. The qualitative study protocol was approved by the ethics committee "Terre d'Éthique", University Hospital Center of Saint-Etienne, France (ref. IRBN962023/CHUSTE) on September the 10th, 2023.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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